Department of the Navy
Human Research Protection Program

Directions for Applying for DoD-Navy Addendum to Federalwide Assurance of Protection for Human Subjects For Institutions Conducting or Collaborating in DON-supported Human Subject Research

Background

Federal regulations, Department of Defense (DoD) directives, and Department of Navy (DON) instructions require institutions seeking to conduct research with human subjects to provide written assurance that they will comply with relevant human research protections requirements. The DoD delegates authority for assurance approval to the DON for DON-supported research. The Surgeon General of the Navy approves DoD-Navy Assurances and may accept other federal assurances.

The Office for Human Research Protections (OHRP) approves Federalwide Assurances (FWA) for institutions conducting research supported by the Department of Health and Human Services.

Institutions with an approved FWA planning to conduct or collaborate in DON-supported human subject research must meet DoD-DON requirements for human subject protections and hold an approved assurance that meets these requirements. The DHHS-approved FWA does not include compliance with DoD and DON requirements.

Procedure for Obtaining a DoD-Navy Addendum to an Institutional FWA

Institutions with FWAs shall meet DoD-DON requirements by:

1. Obtaining a DoD-Navy Assurance in addition to their current FWA.

   [STOP and submit a DoD-Navy Assurance application to the DON HRPP at humanresearch@us.med.navy.mil.]

   OR

2. Obtaining a DoD-Navy Addendum to their current FWA.

   [CONTINUE READING]

An institution applying for a DoD-Navy Addendum must designate the Institutional Review Board(s) (IRB) that will review and approve research under its jurisdiction. An institution may designate:

1. its own IRB(s),
2. DON IRB(s),
3. other U.S. federal IRB(s),
4. other institution's IRB(s), and/or
5. independent IRB(s).

Institutions must ensure that all personnel reviewing, approving, conducting, overseeing, or monitoring DON-supported human subject research comply with these requirements. Institutions must provide their personnel with appropriate initial and continuing training to meet these requirements. Institutions remain responsible for monitoring research with human subjects.

Step-by-step Directions

1. Fill in the required information at the top of the first page and print on institutional letterhead.

2. Part 2 – Institutional Affirmation
Select the appropriate Part 2 version (there are two) and delete the other depending on the institution's IRB arrangement.

a. FWA Institution with its own IRB:

1) The Institutional Official, the Primary Contact – Human Research Protections, and the IRB Chair(s) who signed the institution's FWA must sign the DoD-Navy Addendum.

OR

b. FWA Institution relying on another institution's IRB(s) or independent IRB(s):

1) The Institutional Official and the Primary Contact – Human Research Protections who signed the institution's FWA and are submitting the DoD-Navy Addendum must sign, AND

2) The Institutional Official and the IRB Chair(s) of the institution with the reviewing IRB must sign the DoD-Navy Addendum.

All signatures must be handwritten if an original document is submitted. Signed and dated originals may be scanned and submitted electronically or via facsimile.

3. Submit the document(s) directly to the DON HRPP.

Department of the Navy
Human Research Protection Program (Code M00R)
Bureau of Medicine and Surgery
2300 E Street NW
Washington, D.C. 20372-5300

FAX: 202-762-0976
Email: humanresearch@us.med.navy.mil

Review of the Addendum

The DON HRPP will determine if institutions meet the assurance requirements prior to the start of the research or the release of funding.

The DON HRPP Assurance Approval Authority will review the Addendum. A new Addendum may be approved, returned for modifications, limited in scope, or disapproved. An Addendum for renewal or update may be approved, returned for modifications, restricted, suspended, or disapproved. The Institutional Signatory Official will be notified of the decision.

Once the Addendum is approved, the DON HRPP will provide to the institution a DoD-Navy Addendum number. The DON HRPP will send copies of the approved Addendum to the signatories (Institutional Signatory Official, IRB Chair(s), and the Human Research Protections Primary Contact).

Institutional Responsibilities After Approval

Institutions are responsible for promptly submitting an updated DoD-Navy Addendum when there are changes to:

1. Institutional Signatory Official
2. IRB Chair(s)
3. Human Research Protection Primary Contact
4. Any changes that may affect meeting the Addendum's requirements

Institutions will submit a DoD-Navy Addendum renewal 60 days prior to the expiration date, even if no changes have occurred, in order to maintain an active, approved Addendum. If an institution's Addendum approval expires prior to re-approval, all research must stop, except when halting research would endanger subjects. There is no grace period.

Failure to maintain a current approved DoD-Navy Addendum may result in restriction, suspension, or termination of the institution's Addendum and restriction, suspension, or termination of the institution's DON-supported human subject research.

Record Keeping

Institutions must maintain the DoD-Navy Addendum and supporting documents available for review by DON HRPP.

References

- The Belmont Report http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm
- 32 Code of Federal Regulations Part 219 (32 CFR 219), Department of Defense Regulations, "Protection of Human Subjects" http://www.dtic.mil/biosys/downloads/32cfr219.pdf

- Department of Defense (DoD) Directives 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-supported Research
- 45 Code of Federal Regulations Part 46, (45 CFR 46) Department of Health and Human Services Regulations, "Protection of Human Subjects" http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- Secretary of the Navy Instruction 3900.39 series, "Human Research Protection Program"
- Title 10 United States Code 980, "Limitations on Use of Humans as Experimental Subjects" http://uscode.house.gov/usc.htm)
- Title 21 Code of Federal Regulations 50, 56, 312, 600, 800, Food and Drug Administration (FDA) regulations
- DoDD 3127.1, "Research Integrity and Misconduct" http://www.dtic.mil/whs/directives/corres/pdf/i32107_051404/i32107p.pdf
- DoDD 6200.2, "Use of Investigational New Drugs for Force Health Protection" http://www.dtic.mil/whs/directives/corres/pdf/d62002_080100/d62002p.pdf